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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,252	08/02/2001	Anne Hover	A227.12-0057	9889

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No. 09/921,252	Applicant(s) HOVER ET AL.	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-47 is/are allowed.
- 6) ☒ Claim(s) 1-10 and 35-44 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 39 recites the limitation "the first insert" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 40 recites the limitation "the first insert" in line 1. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 41, depends from itself. A claim cannot depend from itself. Claim 41 has been examined as if it depends from claim 35.

6. Claim 42 recites the limitation "the first insert" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-12 and 35-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,296,645 to Hover et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim an intramedullary nail formed of metal with a non-metal spacer.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-10, 35-38 and 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,935,127 to Border.

Regarding claims 1-5, 7, 8 and 42, Border discloses an intramedullary nail comprising a nail structure extending longitudinally and formed of metal (nail 10), the nail structure having a distal end with a tip for insertion into the medullary canal, with a first window defined in its exterior side of the distal end of the nail structure (Column 4 lines 23-31) extending through the nail to form a second window (slot 17), the first and second window having a longitudinal length and a window width which is less than the longitudinal length (FIG. 1 slot 17); wherein the nail structure defines a cannula therein (bore 16); and a first and second spacer formed of a single non-metal, bioresorbable (Column 2 lines 45-47) material (material 19).

Regarding claim 6, Border discloses a bend in the nail structure (Column 2 lines 61-65).

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Regarding claim 9, Border discloses that the first spacer fills the first window prior to anchoring of a bone fastener (Column 2 lines 45-49 and Column 3 lines 3-9).

Regarding claim 10, Border discloses an additional bone attachment hole defined in the proximal end of the nail structure (bore 22).

Regarding claim 35 and 36, Border discloses that the spacer is formed of a non-metal material separately from the nail structure, the first spacer having outer dimensions which correspond to the first window shape, such that the first window shape, such that the first spacer is insertable into the first window and received by the first window to secure the first spacer relative to the nail structure (Column 2 lines 45-49).

Regarding claim 38, Border discloses that the bone fastener (fastener 34) has a thickness less than the first window longitudinal length and a width which is less than the first window (FIG. 3 and Column 2 lines 37-39).

Regarding claim 40, Border discloses that the first insert fills the first window prior to anchoring a bone fastener transversely through the first insert (Column 3 lines 38-56).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Border '127. Border discloses the claimed invention except for the step of securing the spacer with a snap or press fit. Border discloses that the solid resorbable portion of the nail is secured to the nail by any suitable

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means (Column 2 lines 45-49). There is no indication that the resorbable material isn't formed and then inserted through the bore or transversely through the slot in the side of the nail. Snap fits and press fits are well known ways of securing two separate devices together. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the spacer and then insert the spacer of Border using a snap fit or a press fit since these are well-known techniques of securing separate items together in the mechanical and surgical arts.

Allowable Subject Matter

13. Claims 45, 46 and 47 are allowed.
14. Claims 41, 43 and 44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
15. Claims 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
16. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a second opening adjacent a bioresorbable insert, and a second insert formed separately from the first insert, the second insert having different mechanical or chemical treatment properties than the first insert.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

JRB
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July 24, 2003

David O. Reip
DAVID O. REIP
PRIMARY EXAMINER